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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,225	02/14/2002	Fernando Donate	38342-178463	6196

7590 07/28/2004

Venable
P.O. Box 34385
Washington, DC 20043-9998

EXAMINER	
BLANCHARD, DAVID J	
ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/074,225	DONATE ET AL.	
	Examiner	Art Unit	
	David J Blanchard	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

    1. Claims 1, 5-6, 11-15 and 49 in part and claims 7-10, drawn to the human HPRG polypeptide of SEQ ID NO:5 and a sequence variant of SEQ ID NO:5, classified in class 530, subclass 350.

    2. Claims 1, 5-6, 11-15 and 49 in part and claims 7-10, drawn to the rabbit HPRG polypeptide of SEQ ID NO:6 and a sequence variant of SEQ ID NO:6, classified in class 530, subclass 350.

    3. Claims 1, 5-6, 11-15 and 49 in part and claims 2 and 7-10, drawn to the pentapeptide of SEQ ID NO:7 and addition variant thereof, classified in class 530, subclass 330.

    4. Claim 5 in part, drawn to the human HPRG protein of SEQ ID NO:1 or a homologue of SEQ ID NO:1, classified in class 530, subclass 350.

    5. Claim 5 in part, drawn to the rabbit HPRG protein of SEQ ID NO:3 or a homologue of SEQ ID NO:3, classified in class 530, subclass 350.

    6. Claims 3, 5-15 and49 in part, drawn to a chemically synthesized peptide multimer of SEQ ID NO:8 having the formula P^1n, classified in class 530, subclass 324.

7. Claims 3, 5-15 and 49 in part, drawn to a chemically synthesized peptide multimer of SEQ ID NO:9 having the formula P^1n, classified in class 530, subclass 324.

8. Claims 3, 5-15 and 49 in part, drawn to a chemically synthesized peptide multimer of SEQ ID NO:10 having the formula P^1n, classified in class 530, subclass 324.

9. Claims 3, 5-15 and 49 in part, drawn to a chemically synthesized peptide multimer of SEQ ID NO:8 having the formula $(P^1\text{-}X_m)_n\text{-}P^2$, classified in class 530, subclass 323.

10. Claims 3, 5-15 and 49 in part, drawn to a chemically synthesized peptide multimer of SEQ ID NO:9 having the formula $(P^1\text{-}X_m)_n\text{-}P^2$, classified in class 530, subclass 323.

11. Claims 3, 5-15 and 49 in part, drawn to a chemically synthesized peptide multimer of SEQ ID NO:10 having the formula $(P^1\text{-}X_m)_n\text{-}P^2$, classified in class 530, subclass 323.

12. Claims 4, 5-15 and 49 in part, drawn to a chemically synthesized peptide multimer of SEQ ID NO:8 having the formula $(P^1\text{-}Gly_z)_n\text{-}P^2$, classified in class 530, subclass 350.

13. Claims 4, 5-15 and 49 in part, drawn to a chemically synthesized peptide multimer of SEQ ID NO:9 having the formula $(P^1\text{-}Gly_z)_n\text{-}P^2$, classified in class 530, subclass 350.

14. Claims 4, 5-15 and 49 in part, drawn to a chemically synthesized peptide multimer of SEQ ID NO:10 having the formula $(P^1\text{-}Gly_z)_n\text{-}P^2$, classified in class 530, subclass 350.

15. Claim 16 in part and claims 18-22 drawn to an antibody that binds the HPRG polypeptide of SEQ ID NO:5, classified in class 530, subclass 387.1.

16. Claim 16 in part and claims 18-22 drawn to an antibody that binds the HPRG polypeptide of SEQ ID NO:6, classified in class 530, subclass 388.1.

17. Claim 17 in part and claims 18-22 drawn to an antibody that binds the HPRG polypeptide of SEQ ID NO:8, classified in class 530, subclass 387.3.

18. Claim 17 in part and claims 18-22 drawn to an antibody that binds the HPRG polypeptide of SEQ ID NO:9, classified in class 530, subclass 387.9.

19. Claim 17 in part and claims 18-22 drawn to an antibody that binds the HPRG polypeptide of SEQ ID NO:10, classified in class 530, subclass 391.7.

20-31. Claim 23 in part, drawn to a method for inhibiting cell migration, cell invasion, cell proliferation or angiogenesis, or for inducing apoptosis with a therapeutic composition comprising a HPRG polypeptide or HPRG peptide multimer selected from Groups 1-3

and 6-14, respectively, classified in class 530, subclass 350, for example.

32-44. Claim 24 in part, drawn to a drawn to a method for treating a subject having a disease associated with undesired cell migration, invasion, proliferation, or angiogenesis comprising administering a HPRG polypeptide or a HPRG peptide multimer of Groups 1-3, 6-14, respectively, classified in class 530, subclass 300, for example.

45-50. Claim 25 in part, drawn to an in vitro method for stimulating angiogenesis in cells comprising providing an antibody or fragment thereof of Groups 15-19, respectively, classified in class 424, subclass 139.1, for example.

51-55. Claim 26 in part, drawn to an in vivo method of stimulating angiogenesis in a subject comprising administering an antibody or fragment thereof of Groups 15-19, respectively, classified in class 424, subclass 133.1.

56-60. Claim 27 in part and claims 28-29, drawn to an in vitro method for detecting the presence of HPRG in a biological sample comprising contacting the sample with an antibody or fragment thereof of Groups 15-19, respectively, classified in class 435, subclass 7.92.

61-65. Claim 27 in part and claims 28 and 30-31, drawn to a method (in vivo/in vitro) for detecting the presence of HPRG in a biological sample comprising contacting the sample with an antibody or

fragment thereof of Groups 15-19, respectively, classified in class 435, subclass 7.1.

66-70. Claim 27 in part and claims 28 and 32, drawn to an in vivo method for detecting the presence of HPRG in a biological sample comprising contacting the sample with an antibody or fragment thereof of Groups 15-19, respectively, classified in class 424, subclass 9.1

71-76. Claim 33 in part and claims 34-40, drawn to DNA, vectors and host cells, wherein the DNA encodes a polypeptide of Groups 1-3 and 12-14, respectively, classified in class 536, subclass 23.5.

77-82. Claim 41 in part and claim 42, drawn to a method for providing to a cell, tissue or organ inhibitory amount of a HPRG polypeptide or HPRG peptide multimer comprising administering a vector comprising DNA encoding a polypeptide of Groups 1-3 and 12-14, respectively, classified in class 514, subclass 44.

83-88. Claim 43 in part and claim 44, drawn to a method for providing to a cell, tissue or organ inhibitory amount of a HPRG polypeptide or peptide multimer comprising contacting said cell, tissue or organ with a cell transformed or transfected with a DNA encoding a polypeptide of Groups 1-3 and 12-14, respectively, classified in class 435, subclass 69.1.

89-94. Claim 45 in part and claims 47-48, drawn to an in vivo method for inhibiting angiogenesis in a subject comprising administering an

effective amount of an expression vector comprising DNA encoding a polypeptide of Groups 1-3 and 12-14, respectively, classified in class 514, subclass 44.

95-100. Claim 46 in part, drawn to an in vivo method for inhibiting angiogenesis in a subject comprising administering a cell transformed or transfected with a DNA encoding a polypeptide of Groups 1-3 and 12-14, respectively, classified in class 435, subclass 69.1.

101-112. Claim 50 in part, drawn to a method for isolating a HPRG-binding molecule using an HPRG polypeptide or HPRG peptide multimer (affinity ligand) selected from Groups 1-3 and 6-14, respectively, classified in class 435, subclass 7.1.

113-124. Claim 51 in part, drawn to a method for isolating or enriching cells expressing an HPRG-binding site or receptor from a cell mixture using an HPRG polypeptide or HPRG peptide multimer (affinity ligand) selected from Groups 1-3 and 6-14, respectively, classified in class 435, subclass 7.21.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-19 and 71-76 represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different

functions and different effects. The antibodies of Groups 15-19, the polynucleic acids of Groups 71-76, the polypeptide and peptide multimers of Groups 1-14 are all structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis, while the polypeptide is made by translation of mRNA, the antibody is raised by immunization. Furthermore, the polynucleotide can be used for hybridization screening, the antibody can be used to purify the antigen, for example. The antibodies of Groups 15-19 are patentably distinct because the antibodies of Groups 15-19 bind structurally different polypeptides (SEQ ID NOS:5, 6, 8, 9 and 10, respectively). The antibody of Group 15 binds the polypeptide of SEQ ID NO:5 and the antibody of Group 16 does not, for example. Likewise the DNA's of Groups 71-76 are patentably distinct because the DNA's of Group 71-76 encode different polypeptides, and the polypeptide encoded by the DNA of Group 71 is not encoded by the DNA of Group 72, for example. The polypeptides and peptide multimers of Groups 1-15 are patentably distinct because each is structurally distinct and art on one would not necessarily be art on the others. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions 1-19 and 71-76 are patentably distinct.

The methods of Inventions of Groups 20-70 and 77-124 differ in the method objectives, method steps and parameters and in the reagents used. Inventions 20-31 recite a method for inhibiting cell migration, cell invasion, cell proliferation or angiogenesis, or for inducing apoptosis; Inventions 32-44 recite a

method for treating a subject having a disease associated with undesired cell migration, invasion, proliferation, or angiogenesis; Inventions 45-50 recite an in vitro method for stimulating angiogenesis in cells using an antibody; Inventions 51-55 recite a an in vivo method of stimulating angiogenesis in a subject using an antibody; Inventions 56-60 recite an in vitro method for detecting the presence of HPRG in a biological sample; Inventions 61-65 recite a method (in vivo/in vitro) for detecting the presence of HPRG in a biological sample using an antibody; Inventions 66-70 recite an in vivo method for detecting the presence of HPRG in a biological sample; Inventions 77-82 recite a method for providing to a cell, tissue or organ inhibitory amount of a HPRG polypeptide or HPRG peptide multimer; Inventions 83-88 recite a method for providing to a cell, tissue or organ inhibitory amount of a HPRG polypeptide or HPRG peptide multimer comprising administering a vector comprising DNA encoding a polypeptide of Groups 1-3 and 12-14; Inventions 89-94 recite an in vivo method for inhibiting angiogenesis in a subject comprising administering an effective amount of an expression vector comprising DNA encoding a polypeptide of Groups 1-3 and 12-14; Inventions 95-100 recite an in vivo method for inhibiting angiogenesis in a subject comprising administering a cell transformed or transfected with a DNA encoding a polypeptide of Groups 1-3 and 12-14; Inventions 101-112 recite a method for isolating a HPRG-binding molecule using an HPRG polypeptide or HPRG peptide multimer (affinity ligand) selected from Groups 1-3 and 6-14; Inventions recite a method for isolating or enriching cells expressing an HPRG-binding site or receptor from a cell mixture using an HPRG polypeptide or HPRG peptide

multimer (affinity ligand) selected from Groups 1-3 and 6-14. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, inventions of Groups 20-70 and 77-124 are separate and distinct in having different method objectives, method steps and different endpoints and are patentably distinct.

The inventions of Groups 20-70 and 77-124 are directed to methods that recite structurally and functionally distinct elements and are not required one for the other. The inventions of Groups 20-31, 32-44, 77-82, 83-88, 89-94, 95-100, 101-112 and 113-124 require structurally and chemically distinct polypeptides and peptide multimers, which are not required one for the other. The inventions of Groups 45-50, 51-55, 56-60, 61-65 and 66-70 are directed to methods that recite antibodies that bind structurally and chemically distinct polypeptides and peptide multimers, which are not required one for the other. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of Groups 20-70 and 77-124 are separate and distinct in having different method objectives, method steps and parameters and in the reagents used, and are patentably distinct.

Inventions 1-3, 6-14 and 20-44, 77-88, 101-124 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed

can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide and peptide multimers can be used in a materially different method such as to isolate a HPRG-binding molecule (Groups 101-112) or cells expressing an HPRG polypeptide (Groups 113-124) in addition to the materially different methods of treatment and detection of Groups 20-44 and 77-88.

Inventions 15-19 and 45-70 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group 15 can be used in a materially different method such as to purify the antigen in addition to the materially different methods of Groups 45-70.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

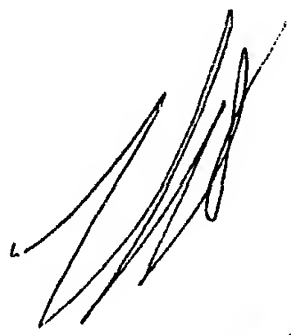
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at Monday through Friday from 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787. The

official fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
David J. Blanchard
571-272-0827



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